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TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY DOCKET NUMBER 7388/84495



US Appln No.: Not Yet Assigned

INTERNATIONAL APPLn.NO.: PCT/JP2004/007403 INTERNATIONAL FILING DATE

International Filing Date: 24 May 2004

PRIORITY DATE CLAIMED
23 May 2003

TITLE OF INVENTION

TRANSDERMAL FORMULATION FOR EXTERNAL APPLICATION CONTAINING NON-STEROIDAL ANTI-INFLAMMATORY ANALGESIC, AND INTERLEUKIN- 1α PRODUCTION INHIBITOR

APPLICANT(S) FOR DO/EO/US

Atsutoshi IKESUE, Kazuhisa YOSHITAKE, Kenji ATARASHI, Koichi IKESUE, Michinori SAKAI, Amarender REDDY, Yoshiteru MOTOKI, Dange VEERAPANENI

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

- 1. Mark This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.
- 2. D This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.
- This express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. Please do not delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
- A copy of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a.

 is attached hereto (required only if not communicated by the International Bureau).
 - b.

 has been communicated by the International Bureau.
 - c. \Box is not required, as the application was filed in the United States Receiving Office (RO/US).
- 6. Man English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a.

 is attached hereto.
 - b.

 has been previously submitted under 35 U.S.C. 154(d)(4).
- 7. _ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
 - a. 👱 are attached hereto (required only if not communicated by the International Bureau).
 - b.

 have been communicated by the International Bureau.
 - c. $\underline{\underline{\square}}$ have not been made; however, the time limit for making such amendments has NOT expired.
 - d.
 have not been made and will not be made.
- 8. 🚇 An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
- 9.

 An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
- 10.

 An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 20. below concern document(s) or information included:

- 11.

 An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
- 12.

 An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.

	e foll	wing feestares	ulbmitted!						Appl	icant use	Office use only
<u> </u>	a)	Basic national	fee \$300.00						\$	300.00	
՛≅	b) Examination fee \$200.00								\$	200.00	
፟	c)	International Se	earch Report prepa	ared by ar	ı ISA c	other than the	us		\$	400.00	
		and provided to	o the Office or prev \$400.00	iously cor	nmuni	cated to the U	S by				
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	OF A	ABOVE CALCUI	LATIONS =						\$	1,100.00	
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A check in the amount of \$_____ to cover the above fees is enclosed.

b. Blease charge my Deposit Account No. 06-1135, regarding our **Order No. 7388/84495**, in the amount of \$\(\frac{1,100}{} \) to cover the above fees. A duplicate copy of this sheet is enclosed.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 06-1135 regarding **Order No. 7388/84495**. A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO: CUSTOMER No. 42798

FITCH, EVEN, TABIN & FLANNERY 1801 K Street, NW, Suite 401L Washington, DC 2006-1201 Telephone: (202) 419-7000 Facsimile: (202) 419-7007

NAME: Kendrew H. Colton, Reg. No. 30,368 Samuel P. Burkholder, Reg. No. 40,541

Date: November 22, 2005

ATTORNEY DOCKET NUMBER 7388/84495

<u> </u>		
13. 🛚	<u>8</u>	A preliminary amendment TO BE ENTERED BEFORE CALCULATING FEES DUE.
14. 🛚	8	An Application Data Sheet under 37 CFR 1.76.
15. 0	0	A substitute specification.
16. <u>c</u>	2	A power of attorney and/or change of address letter.
17. <u>c</u>	_	A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821-1.825.
18. 🛚	2	A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. 🛚	_	A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. 🛚	<u> </u>	Other items or information:
		International Search Report (PCT/ISA/210)
		PCT Notification Concerning Submission of Transmittal of Priority Document (PCT/IB/304)
		PCT Notice Informing the Applicant of the Communication of the International Application to the Designated Offices (PTO/IB/308)
		Copy of Front Page of WO 2004/112837 A1

INTERNATIONAL APPLICATION NO. PCT/JP2004/007403

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Atsutoshi IKESUE et al.

New 371 Patent Application

Filed: Herewith, November 22, 2005

Attorney Docket No.: 7388/84495

Confirmation No.: Not Yet Assigned

Customer No.: 42798

Title:

TRANSDERMAL **FORMULATION** FOR **EXTERNAL APPLICATION** CONTAINING NON-STEROIDAL ANTI-INFLAMMATORY ANALGESIC, AND

INTERLEUKIN-1 a PRODUCTION INHIBITOR

GENERAL AUTHORIZATION FOR PETITION FOR EXTENSION OF TIME UNDER 37 C.F.R. §1.136(a)(3)

MAIL STOP PCT Commissioner for Patents Customer Service Window Randolph Building 401 Dulany Street Alexandria, VA 22314

Sir:

Applicant(s) hereby request under 37 C.F.R. §1.136(a)(3) by this general authorization that any concurrent or future reply submitted by Applicant(s) to the United States Patent and Trademark Office for the above-identified patent application requiring a petition for an extension of time under §1.136(a) for its timely submission be treated as incorporating therein a petition for an extension of time for the appropriate length of time.

If Applicant(s) do not timely pay for any extension fee(s) pursuant to 37 C.F.R. §1.136(a) which may become due for this application under 37 C.F.R. §1.17 by check, the Commissioner is hereby authorized to charge such fee(s), and any additional fees which may be required in this application under 37 C.F.R. §§1.16-1.17 during its entire pendency, or credit any overpayment, to Deposit Account No. 06-1135.

Respectfully submitted,

Fitch, Even, Tabin & Flannery

Date: November 22, 2005

Kendrew H. Colton, Reg. No. 30,368 Samuel P. Burkholder, Reg. No. 40,541

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LAP20 Rec'd PCT/PTO 22 NOV 2005

APPLICATION UNDER UNITED STATES PATENT LAWS

Atty. Dkt. No. 7388/84495

Invention: TRANSDERMAL FORMULATION FOR EXTERNAL APPLICATION

CONTAINING NON-STEROIDAL ANTI-INFLAMMATORY

ANALGESIC, AND INTERLEUKIN-1α PRODUCTION INHIBITOR

Inventor(s): Atsutoshi IKESUE

Kazuhisa YOSHITAKE Kenji ATARASHI Koichi IKESUE Michinori SAKAI Amarender REDDY Yoshiteru MOTOKI Dange VEERAPANENI

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This is a:

- PCT National Phase Application
 - The complete disclosure of PCT/JP2004/007403, filed May 24, 2004 is incorporated by reference.

SPECIFICATION